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DIPLOMATE, AMERICAN BOARD OF ANESTHESIOLOGY

May 23, 1999

3503 '99 MAY 27 P12:47

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 99D-0557

Dear Sirs:

On April 6, 1999, the FDA banned nonhuman primate xenografts because of the potential patient and public exposure to "significant infectious disease risk". However, your guidelines ignored the dangers of xenografts using other species. Since transgenic pigs are considered the source animal of choice for xenotransplants and it is clear that pigs are not any safer than nonhuman primates, it is vital that the FDA ban xenotransplantation from all nonhuman species.

We already know of more than 25 diseases in pigs that can infect humans and more pig viruses are discovered all the time. The Malaysian "Nipah" virus infected over 250 humans, killing 100 and the influenza virus of 1918, which resembled a common swine flu, killed more people in modern history than any other epidemic.

There are safer, more cost-effective, and humane alternatives to xenotransplantation that are being ignored. It make much more sense to prevent disease to reduce the need for transplants in the first place. And if transplants are needed, much can be done to increase the pool of human organs, as many European countries are doing successfully. Indeed, a 1998 GAO report on organ donations showed an untapped donor pool of 150,000 people annually!

In addition to all the research costs, who will pay the costs of breeding, housing, feeding, medicating, screening, transporting, rendering, and disposing of the waste and remains of herds of transgenic pigs? Not to mention that the EPA is already placing new restrictions on livestock pollution because whole communities have been environmentally damaged by pig farms. Should we be contributing to that problem?

Immediate costs aside, there are long term costs as well. Xenograft recipients and their close contacts would require life-long monitoring for signs of infection. The FDA wants to establish a multi-million dollar registry and archive to house blood and tissue from source animals and patients for at least 50 years, at taxpayer expense. I certainly do not want my tax dollars being used in this manner! Who will be held accountable if a zoonotic virus spreads to the human population?

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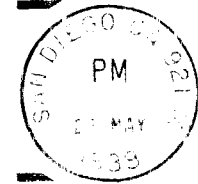
Given that over 45 million Americans lack basic health care, I feel that this is a total waste of taxpayer money. Given the inherent risks involved, I feel that this is unconscionable! I want the Department of Health and Human Services to ban xenotransplantation, from all nonhuman species immediately.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark C. Niblack', with a stylized flourish at the end.

Mark C. Niblack, M.D.

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